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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,808	07/21/2000	Jan-Heiner Kupper	4121-115	2937

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/10/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/446,808

Applicant(s)

KUPPER ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Response/amendment filed 9-27-02 has been received and entered.
2. Amendments to claims 2, 10 and 16 have been entered.
3. Amendments to the specification have been entered.
4. New claims 17-20 have been entered.

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 2-6, 10-16 and 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claimed invention is directed to a transgenic mammal and a method of screening using the transgenic mammal, which encompasses a human, a non-statutory matter. Amending the claim to a transgenic non-human mammal will obviate the rejection.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-6, 10-16 remain rejected and claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 11-8-01.

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9. Claims 3-6 and 10-16 remain rejected and claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: (i) a transgenic mouse, wherein a DNA construct comprising the human cytokeratin-14 promoter operably linked to the coding sequence of the DNA binding domain of human poly (ADP ribose) polymerase (EC.2.4.2.30) and polyadenylation signal of the human cytokeratin-14 gene is integrated into the genome of the transgenic mouse and wherein said DNA construct is the DNA construct of figure 1 and wherein said DNA construct expresses a dominant negative poly(ADP ribose) polymerase in the cells of the basal layer of the skin of the transgenic mouse and wherein in said cells of the basal layer of the skin, the poly(ADP ribose) polymerase is inhibited by the dominant negative poly(ADP ribose) polymerase expressed by the DNA construct and (ii) a method of identifying carcinogenic agents, comprising topically administering one or more potential carcinogenic agents to the transgenic mouse, wherein, when said topical administering of said one or more potential carcinogenic agents to said transgenic mouse, compared to the transgenic mouse not administered the one or more potential carcinogenic agents, results in the development of skin tumors, said one or more potential carcinogenic agent is considered a carcinogenic agent, does not reasonably provide enablement for any and all transgenic mammals and other claimed embodiments encompassed by the claimed invention for reasons of record set forth in the previous office action of 11-8-01. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the claimed invention commensurate in scope with these claims.

### ***Response to Arguments***

Applicant's arguments filed 9-27-02 have been fully considered but they are not persuasive. Applicants argue that making of transgenic animals is standard procedure and is currently in use in thousands of laboratories worldwide. Furthermore, applicants argue that there will be certain variability because living animals are involved and that it is fundamental knowledge that screening of

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animals will follow after making the animals and that using art recognized techniques, an artisan of skill could produce the animals. However, none of the se arguments address the unpredictability issue recognized in the state of the art of making transgenic mammals and discussed in the previous office. Additionally, applicants' arguments do not make the method of making a transgenic mammal routine, rather the state of the art of making transgenic mammals is recognized to be unpredictable. Applicants did not address the written description and enablement rejections separately and therefore, applicants' arguments have been addressed together.

10.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11.Claim 6, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 15 and 17 are indefinite because it recites "figure 1" and the metes and bounds of the claimed invention is not clear. Reciting the description of figure 1 in the claims will obviate the rejection.

12.No claim is allowed.

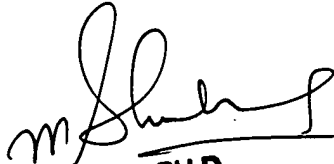
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this

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application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632